I hereby certify that this correspondence is being electronically filed in the United States Patent and Trademark Office on August 25, 2009.

David Saliwanchik

David R. Saliwanchik, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. SPO.121

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	10/535,585
Conf. No.	:	7558
Applicants	:	Hisae Kume, Makoto Yamaguchi, Kenji Mizumoto, Hajime Sasaki
Issued	:	July 21, 2009
Patent No.	:	7,563,458
For	:	Nutritional Compositions for Nutritional Management of Patients with Liver Disease (as amended)

ATTN: CERTIFICATES OF CORRECTION BRANCH
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:	**Application Reads:**
Column 3, Line 41: "licheniformis"	Page 5, Line 9: --licheniformus--
Column 4, Line 4: "licheniformis"	Page 5, Line 36: --licheniformus--
Column 18, Line 52: "IFN-7"	Page 30, Line 11: --IFN-γ--

A true and correct copy of pages 5 and 30 of the specification as filed which supports Applicants assertion of errors on the part of the Patent Office accompanies this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

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DRS/lae
Attachments: Certificate of Correction
Copy of pages 5 and 30 of the specification

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,563,458 Page 1 of 1

APPLICATION NO.: 10/535,585

DATED : January 28, 2004

INVENTORS : Hisae Kume, Makoto Yamaguchi, Kenji Mizumoto, Hajime Sasaki

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3,
Line 41 "licheniformis" should read --licheniformus--.

Column 4,
Line 4 "licheniformis" should read --licheniformus--.

Column 18,
Line 52 "IFN-7" should read --IFN-γ--.

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fermented milk-derived protein is from a composition in which the whey in fermented milk has been reduced;

(4) the nutritional composition according to (1), wherein said fermented milk-derived protein is from fresh cheese;

(5) the nutritional composition according to (4), wherein said fresh cheese is quark;

(6) the nutritional composition according to (1), wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with alkalase from *Bacillus licheniformus*, and trypsin from a porcine pancreas;

(7) the nutritional composition according to (6), which is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000;

(8) the nutritional composition according to (7), wherein the chromatogram from reverse phase HPLC separation is shown in Fig. 1;

(9) a nutritional composition for patients under high levels of invasive stress, wherein said nutritional composition comprises: a milk protein hydrolysate and a protein derived from fermented milk as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate;

(10) the nutritional composition according to (9), wherein said milk protein is selected from the group consisting of casein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI), α-lactoalbumin, β-lactoglobulin, and lactoferrin;

(11) the nutritional composition according to (9), wherein said fermented milk-derived protein is from a composition in which the whey in the fermented milk has been reduced;

(12) the nutritional composition according to (9), wherein said fermented milk-derived protein is from fresh cheese;

(13) the nutritional composition according to (12), wherein said fresh cheese is quark;

(14) the nutritional composition according to (9), wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with alkalase derived from *Bacillus licheniformus*, and trypsin from a porcine pancreas;

reflect hepatic dysfunction rather than inflammation (Gastroenterology, 103: 264-274, 1992). In chronic type B hepatitis patients, IL-1 production is enhanced and correlates with the extent of hepatic fibrosis, and IL-1 is reported to be important in the progression to liver cirrhosis (Gastroenterology, 94: 999-1005, 1988).

Regarding the relationship between liver disease and IL-6

In alcoholic liver cirrhosis, increases in blood IL-6 levels and in IL-6 production in peripheral blood monocytes correlates positively with IgA levels, and negatively with IL-2 and IFN-γ production (Clin. Exp. Immunol., 77: 221-225, 1989). Blood IL-6 activity also increases during acute exacerbation of chronic hepatitis (Am. J. Gastroenterol., 86: 1804-1808, 1991). Blood IL-6 levels and IL-6 production by non-stimulated peripheral blood monocytes is thought to reflect the extent of individual liver inflammation.

In acute viral hepatitis, IL-6 is detected in sinusoidal endothelial cells, Kupffer cells, and invasive monocytes (J. Clin. Pathol., 45: 408-411, 1992). In chronic hepatitis, IL-6 is mainly detected in invasive lymphocytes and fibroblasts in the portal vein region. Therefore, in acute and chronic liver disease, IL-6 expression is predicted to be closely related to inflammation and immune response, regardless of the cause of the disease. IL-6 promotes the regeneration of hepatocytes, and its excessive production may induce tissue damage and fibrosis.

2. Nutrition administration route and cytokine production

To prevent metabolic and organ disorders caused by cytokines during invasive stress, it may be reasonable to induce normal production of cytokines locally while preventing them from spreading to the whole body. Therefore, differences in nutritional administration methods are being discussed with regards to the possibility of modifying cytokine production during invasive stress. In healthy adults who are not under invasive stress, administration of enteral nutrition or intravenous nutrition for one week does not